

K960569

510(k) Notification ERBE Disposable Patient
Return Electrode

February 2, 1996

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Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of BMDA 1990.

For more than 50 years, high-frequency (HF) surgery has been used to cut and/or coagulate biological tissue using the intrinsic thermal effect of electric current. ERBE has been working intensively during this entire period in the production and distribution of state-of-the-art HF surgical instruments and accessories. The ERBE Disposable Patient Return Electrodes are a key accessory in the efficacious application of HF surgical instruments and are intended to be used primarily with Erbe's range of Electrosurgical Generators but they are also compatible with generators from other manufacturers.

The Erbe electrodes are to be sold with and without a pre-attached cable. Erbe will offer the Return Electrodes without the pre-attached cable as these provide the user the option of purchasing a less expensive item and utilizing a re-usable cable.

Disposable return electrodes have been manufactured and distributed worldwide by ConMed and the ERBE Disposable Return Electrodes utilize the same materials and technology. There are no known adverse reactions or field problems with electrodes utilizing this technology or materials.

It is Erbe's intention to apply for ISO Registration and market this product under the CE mark. It is Erbe policy that all product marketed under the Erbe name are so registered.

Based upon the documents enclosed in this Notification, we believe the ERBE Disposable Patient Return Electrodes are Safe and Effective for their intended purpose when used in accordance with the Instructions for Use.